PHARMACY BOARD[657]

Notice of Intended Action

Proposing rule making related to radiopharmaceuticals and providing an opportunity for public comment

The Board of Pharmacy hereby proposes to amend Chapter 16, "Nuclear Pharmacy Practice," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code section 147.76.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code section 147.76.

Purpose and Summary

The proposed amendment would include a requirement that nuclear pharmacies comply with the minimum standards identified in the United States Pharmacopeia General Chapter 825, which applies to radiopharmaceuticals and will be effective December 1, 2020.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 657—Chapter 34.

Public Comment

Any interested person may submit written comments concerning this proposed rule making. Written comments in response to this rule making must be received by the Board no later than 4:30 p.m. on October 13, 2020. Comments should be directed to:

Sue Mears Board of Pharmacy 400 S.W. 8th Street, Suite E Des Moines, Iowa 50309 Email: sue.mears@iowa.gov

Public Hearing

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1)"b," an oral presentation regarding this rule making may be demanded by 25 interested persons, a governmental subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making action is proposed:

Amend subrule 16.4(6) as follows:

16.4(6) Compliance with laws. Nuclear pharmacies shall comply with all applicable laws and regulations of federal and state agencies, including those laws and regulations governing nonradioactive drugs. Nuclear pharmacies shall comply with all standards identified in the United States Pharmacopeia General Chapter 825.